

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ROBERT D. LOVE, :
Plaintiff, : CIVIL ACTION NO. 09-5199 (MLC)
v. :
ALFACELL CORPORATION, et al., :
Defendants. :
_____ :
MEMORANDUM OPINION

COOPER, District Judge

Plaintiff, Robert D. Love, brings this action against Defendants, Alfacell Corporation ("Alfacell"), Lawrence Kenyon, James Loughlin, Kuslima Shogen, David Sidransky, Paul Weiss, John Brancaccio, Stephen Carter, and Donald Conklin (together with Kenyon, Loughlin, Shogen, Sidransky, Weiss, Brancaccio, and Carter, "Individual Defendants" and, collectively, "Defendants").¹ Love alleges that Defendants: (1) violated Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b) ("Section 10(b)'), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"); (2) violated Section 49:3-71 of the New Jersey Uniform Securities Law, N.J.S.A. § 49:3-71; (3) committed fraud ; (4) committed negligent

¹ Although Love originally named Charles Muniz as a Defendant, Love did not name Muniz as a Defendant in the Amended Complaint. (Compare dkt entry. no. 1, Compl., with dkt entry no. 31, Am. Compl.) The Court will accordingly direct that the action insofar as it was brought against Muniz be terminated.

misrepresentation; and (5) breached various fiduciary duties. (Am. Compl.) Love also alleges that the Individual Defendants: (1) violated Section 20(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78t(a) ("Section 20(b)"); (2) committed fraud; (3) breached various fiduciary duties; (4) committed gross negligence; and (5) committed corporate waste. (Id.)

Defendants move to dismiss the Amended Complaint pursuant to Federal Rule of Civil Procedure ("Rule") 9(b), Rule 12(b)(6), and the Private Securities Litigation Reform Act of 1995, Section 78u-4, et seq. ("PSLRA"). (Dkt. entry no. 32, Mot. Dismiss; dkt. entry no. 33, Defs. Br.) They argue, inter alia, that Love has not presented a claim under Section 10(a) and Rule 10b-5 upon which relief can be granted. (Defs. Brief at 11-17.)² Love opposes the motion. (See dkt. entry no. 36, Plt. Opp. Br.)

The Court, pursuant to Local Civil Rule 78.1(b), decides the motion on the papers. For the reasons set forth below, the Court will: (1) grant the motion with respect to Love's claims under Section 10(b), Rule 10b-5, and Section 20(a), and dismiss such claims with prejudice; and (2) dismiss the remaining state law claims without prejudice to recommence that part of the action in state court.

² The Court, below, discusses the merits of Defendants' arguments and the impact of such arguments upon on Love's Section 20(a) claim. The Court will not, however, discuss Defendants' other arguments in support of the motion because the Court has determined that they are not necessary to resolve the motion.

BACKGROUND

I. Love's Relationship With Alfacell

Alfacell, a Delaware corporation maintaining its principal place of business in Somerset, New Jersey, is a biopharmaceutical company engaged in the discovery, development, and commercialization of therapies for cancer and other diseases.

(Am. Compl. at ¶ 16.) During the periods relevant to this action, Individual Defendants served as Alfacell's corporate officers, members of Alfacell's board of directors, or both.

(Id. at ¶¶ 17-26.)

Love joined Alfacell in May of 2005 as its Vice President and Chief Financial Officer ("CFO"). (Am. Compl. ¶ 9). See also Alfacell Form 8-K, filed on May 26, 2006, at 2.³ As compensation, Love received stock options that vested subject to an established schedule. Upon vesting, the options permitted him to purchase up to 400,000 shares of Alfacell stock at \$1.87 per share. (Am. Compl. at ¶ 10.) See Alfacell Form 8-K, filed on May 26, 2006, at 2. While employed by Alfacell, Love vested

³ The Court, as permitted by the Federal Rules of Evidence, takes judicial notice of several Alfacell SEC filings. See F.R.E. 201; Oran v. Stafford, 226 F.3d 275, 289 (3d Cir. 2000) (noting that Federal Rule of Evidence 201(b)(2) "permits a court, in deciding a motion for judgment on the pleadings, to take judicial notice of properly-authenticated public disclosure documents filed with the SEC."). The SEC provides public access to such documents through its Electronic Data Gathering, Analysis, and Retrieval ("EDGAR") System. EDGAR is available online at <http://www.sec.gov/edgar/searchedgar/webusers.htm>.

interests in and purchased 20,000 shares of Alfacell stock. (Am. Compl. at ¶ 12). He also vested an interest in 125,000 additional shares. His option to purchase these shares, if not exercised, would have expired on July 19, 2007. (Id. at ¶ 11.)

Love worked for Alfacell for approximately twenty months and announced his resignation in November of 2006. (See id. at ¶ 13.) See Alfacell Form 8-K, filed on Nov. 9, 2006, at 2. He ceased working for Alfacell on January 19, 2007. (Am. Compl. at ¶ 13.) Love was not thereafter involved in Alfacell's day-to-day operations and he thus lacked access to "inside information" about Alfacell. (Id. at ¶ 14.)

II. Alfacell's Experimental Cancer Drug, ONCONASE

At all times relevant to this action, Alfacell sought to commercialize ONCONASE, an experimental drug developed to treat unresectable malignant mesothelioma. (Id. at ¶¶ 1, 37). See Alfacell Form 8-K, filed on Oct. 31, 2006, at 4, 7.⁴ To further the development of ONCONASE, Alfacell conducted clinical trials. Such trials served as necessary predicates to the submission of a New Drug Application to the United States Food and Drug Administration ("FDA"). (See Am. Compl. at ¶¶ 34-35).

⁴ Defendants, in support of the motion, submitted portions of the October 31, 2006 filing as an exhibit to the Declaration of Jeffrey A. Simes, Esq. ("Simes Decl."). (Dkt. entry no. 34, Simes Decl., Ex. A.)

Pharmaceutical drug trials traditionally include three phases. (*Id.* at ¶ 33.) Phase I consists of safety studies, administered to healthy volunteers. (*Id.*) Phase II consists of “proof of concept” studies, administered to patients presenting the disease, to determine the new drug’s safety and efficacy, and the optimum therapeutic dose. (*Id.*) Phase III then measures the extent of the new drug’s efficacy and side effects against the standard treatment for a given medical condition, as determined by randomized and/or double-blind trials. (*Id.* at 34.) The endpoint of a Phase III trial is survival, i.e., the length of time that patients enrolled in the study live. Alfacell Form 10-Q, filed June 9, 2006, at 20.⁵ Pharmaceutical drug development companies typically include Phase III trial results with their FDA New Drug Applications. (Am. Compl. at ¶ 34.)

Alfacell established and conducted a Phase III clinical trial between 2006 and 2008, hoping to measure the efficacy and side effects of ONCONASE as compared to standard treatments for unresectable malignant mesothelioma. (*Id.* at ¶ 35.) See Alfacell Form 8-K, Oct. 30, 2006. To achieve statistical significance, it concluded and that the Phase III trial required 316 “patient events,” i.e., patient deaths. (See Am. Compl. at 35.) See Alfacell Form 10-Q, filed June 9, 2006, at 20.

⁵ Defendants submitted portions of the June 9, 2006 filing in support of the motion. (Simes Decl., Ex. B.)

III. Alfacell's Oversight of the Phase III Clinical Trial

During Love's tenure with Alfacell, Alfacell issued five quarterly reports, i.e., SEC Form 10-Q, and two annual reports, i.e., SEC Form 10-K. Each report, which was electronically signed by Love and filed with the SEC, chronicled the progress of the Phase III clinical trial. See Alfacell Form 10-Q, filed Dec. 11, 2006; Alfacell Form 10-K, filed Oct. 16, 2006; Alfacell Form 10-Q, filed June 9, 2006; Alfacell Form 10-Q, filed Mar. 13, 2006; Alfacell Form 10-Q, filed Dec. 12, 2005; Alfacell Form 10-K, filed Oct. 14, 2005; Alfacell Form 10-Q, filed June 9, 2005. Through these reports, Alfacell repeatedly stated that it "could not predict with certainty when a sufficient number of [clinical patient] deaths will occur to achieve statistical significance." Alfacell Form 10-Q, filed Dec. 11, 2006, at 12; Alfacell Form 10-K, filed Oct. 16, 2006, at 27; Alfacell Form 10-Q, filed June 9, 2006, at 13; Alfacell Form 10-Q, filed Mar. 13, 2006, at 11; Alfacell Form 10-Q, filed Dec. 12, 2005, at 10; Alfacell Form 10-K, filed Oct. 14, 2005, at 19; Alfacell Form 10-Q, filed June 9, 2005, at 11; see also Alfacell Form S-3, filed Aug. 16, 2006, at 5.⁶ It clarified that it could not "predict how long it will take us nor how much it will cost us to complete our Phase III trial because it is a survival study . . ." Alfacell Form 10-

⁶ Defendants submitted portions of the August 16, 2006 filing in support of the motion. (Simes Decl., Ex. C.)

Q, filed Dec. 11, 2006, at 12; Alfacell Form 10-K, filed Oct. 16, 2006, at 27; Alfacell Form 10-Q, filed June 9, 2006, at 13; Alfacell Form 10-Q, filed Mar. 13, 2006, at 11; Alfacell Form 10-Q, filed Dec. 12, 2005, at 10; Alfacell Form 10-K, filed Oct. 14, 2005, at 19; Alfacell Form 10-Q, filed June 9, 2005, at 11.⁷ And it further clarified:

According to the [trial] protocol, a sufficient number of patient deaths must occur in order to perform the required statistical analyses to determine the efficiency of ONCONASE® in patients with unresectable (inoperable) malignant mesothelioma. Since it is impossible to predict with certainty when these terminal events in the Phase III trial will occur, we do not have the capability of reasonably determining when a sufficient number of deaths will occur.

Alfacell Form 10-K, filed Oct. 16, 2006, at 18; Alfacell Form 10-Q, filed June 9, 2006, at 19; Alfacell Form 10-Q, filed Mar. 13, 2006, at 19; Alfacell Form 10-Q, filed Dec. 12, 2005, at 17; Alfacell Form 10-K, filed Oct. 14, 2005, at 26; Alfacell Form 10-Q, filed June 9, 2005, at 16.⁸

⁷ Alfacell included this sentence in its June 9, 2005 and March 13, 2006 quarterly reports with minor variations. In the June 9, 2005 filing, it appeared in capital letters. Alfacell Form 10-Q, filed June 9, 2005, at 16. In the March 13, 2006 filing, Alfacell clarified that it was nearing completion of "part two of our Phase III trial[.]" Alfacell Form 10-Q, filed Mar. 13, 2006, at 19 (emphasis added). The sentence did not appear in Alfacell's December 11, 2006 quarterly report.

⁸ Alfacell also included this disclaimer in its August 2006 registration statement and prospectus. Alfacell Form 424B3, filed Aug. 28, 2006, at 5; Alfacell Form S-3, filed Aug. 16, 2006, at 5.

To provide adequate oversight of the Phase III trial, Alfacell created a Research and Clinical Oversight Committee ("the Committee"), which it announced in a February 12, 2007 press release. (Am. Compl. at ¶¶ 38, 40.) Alfacell stated that the Committee would "work closely with management and the scientific advisory board to provide support and direction to the company's research and development programs," thereby providing watchful and responsible care of the Phase III trial. (Id. at ¶¶ 38, 40.)

After creating the Committee, Alfacell continued to advise the SEC and the public of the status of the Phase III trial through its ongoing quarterly and annual reports. Through those reports, it began to cautiously estimate an end-date for the Phase III trial:

The primary endpoint of the trial is overall survival. . . . At this time, we cannot predict with certainty the timing of the occurrence of the required number of deaths, but currently estimate that this will occur in the third quarter of 2007.

(Id. at ¶ 48.) See Alfacell Form 10-Q, filed Mar. 12, 2007.⁹ At a June 5, 2007 investor meeting, Alfacell reiterated its estimate. (Am. Compl. ¶ 49.) The company's acting Chief Executive Officer, Shogen, and its acting CFO, Kenyon, provided information about the creation of the Committee and an estimated

⁹ Defendants submitted portions of Alfacell's March 12, 2007 filing in support of the motion. (Simes Decl., Ex. D.)

(or targeted) end-date for the Phase III trial. (Id. at ¶¶ 41, 49-50.) In a slide deck presented to investors that day, Shogen and Kenyon, on behalf of Alfacell, noted:

This presentation includes statements that may constitute "forward-looking" statements, usually containing the words "believe," "estimate," "project," "expect" or similar expressions. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include the risks discussed in the Company's periodic filings with the Securities and Exchange Commission. . . .

(See Am. Compl. at ¶ 49-50.) See Alfacell Form 8-K, Ex-99.1, filed on June 5, 2007, at 2. Alfacell thereafter noted that it anticipated completing the Phase III trial in the third quarter of 2007. Alfacell Form 8-K, EX-99.1, filed on June 5, 2007 at 2, 25 ("Phase III Results Expected 3rd Quarter 2007").¹⁰

In its next quarterly report, Alfacell repeated its expectation that it would complete the Phase III trial in the third quarter of 2007. Alfacell Form 10-K, filed June 8, 2007, at 18 ("At this time, we cannot predict with certainty the timing of the occurrence of the required number of deaths, but currently estimate that this will occur in the third quarter of 2007.").

¹⁰ Defendants submitted portions of the slides presented at the June 5, 2007 investor meeting in support of the motion. (Simes Decl., Ex. E.)

IV. Love Exercised of His Remaining Stock Options

Love learned of Alfacell's estimate for completion of the Phase III trial. (See Am. Compl. at ¶ 81.) Because Love believed that the estimate for completion of the Phase III trial was reliable, he exercised his remaining stock options on June 17, 2007, two days before they expired. (Id. at ¶¶ 80, 82.) Love thus purchased 125,000 shares for \$1.87 per share, \$0.62 per share below the then-current market price. (Id. at 80).

V. Alfacell Did Not Complete the Phase III Trial as Predicted, But Predicted Completion by Year's End

Through a September 12, 2007 press release, Alfacell announced that the Phase III trial had reached 316 "total events." (Am. Compl. at ¶ 57.) See Alfacell Form 8-K, EX-99.1, filed Sept. 18, 2007, at 1. It further stated, however, that only 290 of the 316 "total events" constituted "evaluable events (patient deaths) [.]" (Am. Compl. at ¶¶ 58-59.) See Alfacell Form 8-K, EX-99.1, filed September 18, 2007, at 1. The remaining twenty-six patients had either not qualified for the study or failed to received at least one dose of ONCONASE. See Alfacell Form 8-K, EX-99.1, filed Sept. 18, 2007, at 1 ("To be considered evaluable, patients must meet all of the eligibility requirements for the study and receive at least one dose of study drug.") Alfacell nevertheless projected that it would reach 316 "evaluable events" before the end of 2007. Id.

In its Annual Report filed in October of 2007, Alfacell reaffirmed its estimate and declared that it would complete the Phase III trial before the end of 2007. Alfacell Form 10-K, filed Oct. 15, 2007, at 5. As before, it tempered the estimate by noting its inability to "predict with certainty when a sufficient number of deaths will occur . . ." Id. at 31.

During an October 15, 2007 earnings call, Kenyon explained that Alfacell had not completed the Phase III trial by its original target date, i.e., during the third quarter of 2007, because

once we got to 316 total events, we were able to determine that some patients had been technically lost to follow-up, meaning that they hadn't been in contact with any of the particular sites where they were treated for an extended period of time. This is not a large number. It's less than 10 but we are taking efforts right now and taking measures to track down those patients and determine their status.

(Am. Compl. at ¶ 64.)

VI. As Alfacell Missed its Targeted End-Date for the Phase III Trial, Love Attempted to Communicate with Alfacell's Directors

Love met with Kenyon in October of 2007 and inquired about the status of the Phase III trials. During that meeting, Kenyon represented that Alfacell still expected to complete the Phase III trial before the end of 2007. (Id. at ¶ 66.)

Alfacell, however, did not complete the Phase III trial by its targeted end-date. Love, as a result, called, sent letters, and sent e-mails to each of the Individual Defendants between September 20, 2007 and February 27, 2008, expressing concern about Alfacell's ability to complete the Phase III trial and requesting more information. (Am. Compl. at ¶¶ 91-98.) Love also sent an e-mail to the Alfacell Board of Directors on February 4, 2008, asking them to hire a Chief Medical Officer ("CMO") to oversee the Phase III trial to ensure its "clinical, regulatory, and fiscal compliance[.]" (Id. at ¶¶ 99, 104.) Kenyon, then acting as a member of Alfacell's Board of Directors and as its Chief Operating Officer, responded by e-mail on March 3, 2008, stating:

Beginning with our conference call in early December, we are no longer in the business of projecting when the final event will occur. Frankly, the timing of when 316 events occurs has become completely irrelevant and I only hear one investor focusing on that issue.

(Id. at ¶ 104.) Kenyon, in a separate e-mail on March 3, 2008, further stated that:

. . . as for projections, a qualified CMO would tell you that we should not have been in the projections business in the first place. There are more effective ways to provide guidance as to clinical trial status.

(Id. at ¶ 105) (emphasis omitted).

Alfacell reached 316 "evaluable events" and, with them, the end of the Phase III trial on April 2, 2008. (Id. at ¶ 89.)

VII. Procedural History of this Action

Love commenced this action on October 9, 2009. (See dkt. entry no. 1, Compl.) After seeking leave of the Court and receiving such leave from the Magistrate Judge, he filed an Amended Complaint on October 10, 2010. (See dkt entry no. 30, Order; Am. Compl.) Through the Amended Complaint, Love seeks compensatory and punitive damages for Defendants' alleged violations of Section 10(b) and Rule 10b-5, Section 20(a), and Section 49:3-71 of the New Jersey Uniform Securities Law, N.J.S.A. § 49:3-71, and for Defendants' commission of acts allegedly constituting fraud, gross negligence, negligent misrepresentation, breach of fiduciary duties, and corporate waste. (Id. at ¶¶ 137-93, 196-99.) He also seeks an accounting from Alfacell. (Id. at ¶¶ 194-95.)

As the Amended Complaint pertains to Defendants' alleged violations of Section 10(b) and Rule 10b-5, Love contends that Defendants knowingly and/or recklessly made and/or disseminated false and misleading statements concerning the creation of the Committee and the completion of the Phase III clinical trial. (Id. at ¶ 139.) He alleges that the Committee discovered that the Phase III clinical trial was flawed because the trial did not incorporate a reliable data management and collection system, or a quality assurance program, and that "Defendants were in exclusive possession of this information and knew for certainty

[sic] that the trial could not complete before 2008." (Id. at ¶¶ 44-45.) He further alleges that Defendants concealed this information "and made false and misleading statements concerning the timeline for the completion of the Phase [III] trial." (Id. at ¶¶ 45, 47.) He finally alleges that he learned for the first time "that Defendants could not accurately project trial completion dates and that Defendants had deliberately mislead [Love] concerning Defendants' timeline for the completion of the Phase [III] trial" upon receiving and reading Kenyon's June 3, 2008 e-mails. (Id. at ¶ 74.)

To support his claim under Section 10b and Rule 10b-5, Love asserts that he relied on Alfacell's alleged misrepresentations and omissions when he purchased and, later, chose not to sell Alfacell stock. (Id. at ¶¶ 81, 83, 142-43.) With respect to the purchase of Alfacell stock, Love claims that his reliance upon Alfacell's misrepresentations and omissions caused him harm because he exercised his stock options and purchased 125,000 shares of Alfacell stock, which subsequently lost value. (Id. at ¶¶ 81-82, 142.) With respect to the sale of Alfacell stock, Love claims that he relied upon Defendants' continued statements regarding the completion of the Phase III trial and that, but for such statements and/or related omissions, he would have known that Alfacell could not complete the Phase III trial before the end of 2007 and he would have sold his shares. (Id. at ¶ 83.)

As the Amended Complaint pertains to the Individual Defendants' alleged violations of Section 20(a), Love contends that the Individual Defendants, as officers and directors of Alfacell, acted as "controlling persons" and are thus liable to Love. (Id. at ¶¶ 146-48. He specifically argues that because Individual Defendants "had direct and supervisory involvement in the day-to-day operations of Alfacell," they "are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations" alleged in the Amended Complaint. (Id. at ¶ 147.)

Defendants filed the motion in response to the Amended Complaint, arguing, inter alia, that Love cannot state a claim under Section 10(b) and Rule 10b-5 upon which relief can be granted. (Mot. Dismiss.) Defendants specifically dispute that Love has adequately pleaded such claims with respect to the elements of falsity, materiality, scienter, and loss causation. (Defs. Br. at 9, 43, 72, 80-81.) They do not argue the merits of Love's claims under Section 20(a). (Id.) Love opposes the motion. (Plt. Opp. Br.)

DISCUSSION

I. Standard of Review

A court may generally dismiss a complaint pursuant to Rule 12(b) (6) for "failure to state a claim upon which relief can be granted." Fed.R.Civ.P. 12(b) (6). In addressing such a motion,

the Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine, whether under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. Cnty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008). At this stage, a

complaint must contain sufficient factual matter, accepted as true to 'state a claim to relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007)). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged--but it has not 'show[n]'--that the 'pleader is entitled to relief.'" Iqbal, 129 S.Ct. at 1950 (quoting Rule 8(a)(2)).

Courts employ a stricter standard, however, when considering a motion to dismiss a securities fraud action. Such actions are governed by Rule 9(b) and the PSLRA, which "require[] more than mere reference to the conventional standard applicable to motions under Rule 12(b)(6)." C.W. Sommer & Co. v. Rockefeller (In re Rockefeller Ctr. Props., Inc.), 311 F.3d 198, 215 (3d Cir. 2002). A claim that fails to meet the requirements of Rule 9(b) and the PSLRA may be defeated by a motion to dismiss. See, e.g., In re Advanta Corp. Sec. Litiq., 180 F.3d 525, 531 (3d Cir. 1999).

Rule 9(b) directs a party "alleging fraud or mistake" to "state with particularity the circumstances constituting fraud or mistake." Fed.R.Civ.P. 9(b). "This particularity requirement has been rigorously applied in securities fraud cases." In re Burlington Coat Factory, 114 F.3d 1410, 1417 (3d Cir. 1997). Though plaintiffs need not plead every material detail of the fraud, Rule 9(b) "requires, at a minimum, that plaintiffs support their allegations of securities fraud with all of the essential factual background that would accompany the first paragraph of any newspaper story - that is, the who, what, when, where and how of the events at issue." Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 144 (3d Cir. 2004) ("Cal.P.E.R.S.").

Plaintiffs alleging securities fraud must also comply with the heightened pleading requirements of the PSLRA. Id. The PSLRA requires plaintiffs to: "(1) specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading[;] and (2) state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind[.]" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 321 (2007) (citing and expounding upon 15 U.S.C. § 78u-4(b)(1)-(2)). This "particularity [requirement] extends that of Rule 9(b) and requires plaintiffs to set forth the details of allegedly fraudulent statements or omissions, including who was involved, where the events took

place, when the events took place, and why any statements were misleading." In re Rockefeller, 311 F.3d at 218.

Taken together, the heightened pleading requirements set forth by Rule 9(b) and the PSLRA have established a standard justifying dismissal of a complaint, apart from dismissal as set forth in Rule 12(b) (6). Cal.P.E.R.S., 394 F.3d at 145; see In re Intelligroup Sec. Litig., 527 F.Supp.2d 262, 276 (D.N.J. 2007) ("In sum, Rule 9(b) and the [PSLRA] modified the traditional Rule 12(b) (6) analysis for the purposes of pleading 'misrepresentation' and 'scienter' elements" of a securities fraud claim.). The Court, when presented with a motion to dismiss a securities fraud claim, thus employs a modified Rule 12(b) (6) analysis, under which the Court disregards "catch-all" or "blanket" assertions that fail to comply with the particularity requirements of Rule 9(b) and the PSLRA. Cal.P.E.R.S., 394 F.3d at 145. "[U]nless plaintiffs in securities fraud actions allege facts supporting their contentions of fraud with the requisite particularity mandated by Rule 9(b) and [the PSLRA], they may not benefit from inferences flowing from vague or unspecific allegations--inferences that may arguably have been justified under a traditional Rule 12(b) (6) analysis." Id.

II. Elements of Claims Raised Under Section 10(b) and Rule 10b-5

Section 10(b) and Rule 10b-5 create liability for securities fraud.¹¹ Section 10(b) provides, in pertinent part, that:

[i]t shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange--

* * *

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j. Rule 10b-5, which establishes a private cause of action for securities fraud, was promulgated by the Securities and Exchange Commission in order to implement Section 10(b).

Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 729 (1975).

Rule 10b-5 makes it unlawful:

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of

¹¹ Before the 1934 Act was codified, the contents of Section 78j appeared in section 10(b) of Public Law 73-291. See 73 Pub.L.No. 291, 48 Stat. 881 (1934). As a result, this provision is commonly referred to as Section 10(b).

the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To state a claim for relief under Section 10(b) and Rule 10b-5, a plaintiff must establish six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." Erica P. John Fund, Inc. v. Halliburton Co., 131 S.Ct. 2179, 2184 (2011) (citations omitted); see also In re Aetna, Inc. Sec. Litiq., 617 F.3d 272, 277 (3d Cir. 2010) (reciting elements and clarifying that "scienter" is "a wrongful state of mind" and that "loss causation" is "a causal connection between the material misrepresentation and the loss."). As noted above, a plaintiff raising such a claim must plead the elements of misrepresentation and scienter with particularity. 15 U.S.C. § 78u-4(b); In re Intelligroup, 527 F.Supp.2d at 277 ("It appears that the heightened pleading requirements of PSLRA are inapplicable to the remaining elements of a 10b-5 claim.").

With respect to the first element, Rule 10b-5 liability may arise either from affirmative misstatements or misleading omissions. Such omissions, however, only give rise to liability where the defendant had an affirmative duty to disclose the information in question, such as "when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete or misleading prior disclosure." Oran v. Stafford, 226 F.3d 275, 285-86 (3d Cir. 2000); see Matrixx Initiatives, Inc. v. Siracusano, 131 S.Ct. 1309, 1321 (2011) ("Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'") (quoting 17 C.F.R. § 240.10b-5(b)). "The task of determining whether a given omission is material is especially difficult when the plaintiff alleges nondisclosure of 'soft' information. The term soft information refers to statements of subjective analysis or extrapolation, such as opinions, motives, and intentions, or forward looking statements, such as projections, estimates, and forecasts." Craftmatic Sec. Litig. v. Kraftsow, 890 F.2d 628, 642 (3d Cir. 1989).

Under Section 10(b) and Rule 10b-5, the Court must analyze each of the statements and omissions at issue to determine whether the plaintiff pleaded, with the requisite particularity, that those statements and omissions constituted material misrepresentations. In re Westinghouse Sec. Litig., 90 F.3d 696,

712 (3d Cir. 1996); see In re Rockefeller, 311 F.3d at 211 (noting that Rule 10b-5 "explicitly require[s] a well-pleaded allegation that the purported misrepresentations or omissions at issue were material.") A fact is material only if "there [is] a substantial likelihood that [it] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available" to the investing public. TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976). The "materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm's stock." In re Merck & Co., Inc. Sec. Litig., 432 F.3d 261, 269 (3d Cir. 2005) (citation omitted) (discussing the efficient market hypothesis).

III. The PSLRA's Safe Harbor for Forward-Looking Statements

The PSLRA contains a safe harbor provision, which protects certain forward-looking statements from Section 10(b) and Rule 10b-5 liability. The safe harbor provision states:

in any private action arising under [the PSLRA] that is based on an untrue statement of a material fact or omission of a material fact necessary to make the statement not misleading, a person . . . shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that-

(A) the forward-looking statement is-

(i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that

could cause actual results to differ materially from those in the forward-looking statement; or

(ii) immaterial; or

(B) the plaintiff fails to prove that the forward-looking statement-

(i) if made by a natural person, was made with knowledge by that person that the statement was false or misleading.

15 U.S.C. § 78u-5(c)(1). Such safe harbor was designed to, inter alia, prevent statements regarding future business plans from causing liability. In re Merck & Co., Inc., 432 F.3d at 272.

The safe harbor provision therefore applies to statements that are forward-looking as defined by the statute, provided that they are "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false and misleading."

In re Aetna, Inc., 617 F.3d at 278-79. Such statements are:

- (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
- (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;

* * *

(D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C) [.]

15 U.S.C. § 78u-5(i)(1).

Cautionary language relating to forward-looking statements must be "extensive and specific[.]" Inst'l Investors Grp. v. Avaya, 564 F.3d 242, 256 (3d Cir. 2009). "[A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation." Id.

IV. Elements of Claims Raised Under Section 20(a)

Section 20(a) creates a private cause of action against individuals who are "control persons" of companies liable for securities fraud. Jones v. Intelli-Check, Inc., 274 F.Supp.2d 615, 644 (D.N.J. 2003).¹² It states:

Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a).

¹² Before the 1934 Act was codified, the contents of Section 78t(a) appeared in section 20(a) of Public Law 73-291. See 73 Pub.L.No. 291, 48 Stat. 881 (1934). As a result, this provision is commonly referred to as Section 20(a).

Section 20 thus imposes liability on individuals who exercised control over a company that committed securities fraud. In re MobileMedia Sec. Litig., 28 F.Supp.2d 901, 940 (D.N.J. 1998). Plaintiffs alleging a Section 20(a) violation "must plead facts showing: (1) an underlying violation by the company; and (2) circumstances establishing defendant's control over the company's actions." Jones, 274 F.Supp.2d at 645. If plaintiffs fail to establish that the company committed an underlying violation, the controlling person(s) of that company therefore cannot be held liable under Section 20(a). In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 287 (3d Cir. 2006); Inst'l Investors Grp., 564 F.3d at 252 ("[L]iability under Section 20(a) is derivative of an underlying violation of Section 10(b) by the controlled person.").

V. Application to this Case

A. Claims Raised Under Section 10(b) and Rule 10b-5

1. Defendants' Allegedly False and Misleading Statements and/or Omissions Concerning the Creation of the Committee

Love asserts that Defendants "intentionally and/or recklessly made . . . materially false and misleading statements[,]" "disseminated materially false and misleading statements, and omitted information concerning the creation of" the Committee. (Am. Compl. at ¶¶ 139-40.) Such claims do not

meet the pleading burdens imposed by the PSLRA and, as such, must be dismissed.

As noted above, a plaintiff's claim for securities fraud must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading[.]" Tellabs, 551 U.S. at 321 (citing 15 U.S.C. § 78u-4(b)) (emphasis added). Although Love has identified three statements regarding the creation of the Committee, he fails to specify whether any or all of these statements are misleading or note the reason(s) why such statements may be misleading. (See Am. Compl. at ¶¶ 38, 40-41 (noting Alfacell announcement of creation of Committee and declaring purpose of Committee to be "to 'work closely with management and the scientific advisory board to provide support and direction to the company's research and development programs' and thereby provide watchful and responsible care of the Phase [III] trial."). The Court will accordingly dismiss Love's claim under Section 10(b) and Rule 10b-5, inasmuch as he relies on these statements and/or omissions.

2. Defendants' Allegedly False and Misleading Statements and/or Omissions Concerning the Completion of the Phase III trial for ONCONASE

Love also asserts that Defendants "knowingly and/or recklessly made and/or disseminated materially false and misleading statements, and omitted material information concerning . . . the completion of the Phase [III] clinical trial

of ONCONASE." (Am. Compl. at ¶ 139.) Love cites to approximately fifteen examples of such misrepresentations and/or omissions. (See Am. Compl. at ¶¶ 45-51, 53, 55-62, 64-66.)

The Court, after carefully examining these statements in the full context of both the Amended Complaint and the total mix of information available to investors, has determined that the Amended Complaint is deficient because Love cannot demonstrate that Defendants' statements and omissions constituted material misrepresentations. The Court will accordingly dismiss the remainder of Love's claim under Section 10(b) and Rule 10b-5.

A plaintiff pursuing a securities fraud action must "show that the statements were misleading as to a material fact. It is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant." Basic Inc. v. Levinson, 485 U.S. 224, 238 (1988). As noted above, a fact is material only if "there [is] a substantial likelihood that [it] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available" to the investing public. TSC Indus., 426 U.S. at 449. Where "alleged misrepresentations and omissions . . . are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality, the allegations are not actionable as a matter of law." In re MobileMedia Sec. Litig., 28 F.Supp.2d at 932. "When assessing materiality, not only the

statement or omission itself but, as well, the context in which it occurs must be considered." Id.

Even assuming arguendo that the statements at issue are false, Love cannot demonstrate that such statements (or omissions) were material because a reasonable investor would not view such statements as altering the total mix of information that was available about Alfacell. See TSC Indus., 426 U.S. at 449. Between June 9, 2005 and December 5, 2006, Alfacell filed multiple Quarterly and Annual Reports that, inter alia, noted that Alfacell "could not predict with certainty when a sufficient number of [clinical patient] deaths [would] occur," such that it could complete the Phase III trial of ONCONASE. Alfacell Form 10-Q, filed Dec. 11, 2006, at 12; Alfacell Form 10-K, filed Oct. 16, 2006, at 27; Alfacell Form 10-Q, filed June 9, 2006, at 13; Alfacell Form 10-Q, filed Mar. 13, 2006, at 11; Alfacell Form 10-Q, filed Dec. 12, 2005, at 10; Alfacell Form 10-K, filed Oct. 14, 2005, at 19; Alfacell Form 10-Q, filed June 9, 2005, at 11; see also Alfacell Form S-3, filed Aug. 16, 2006, at 5. It also noted, repeatedly, that it was "impossible to predict with certainty when [the] terminal events in the Phase III trial will occur[.]" Alfacell Form 10-K, filed Oct. 16, 2006, at 18 (emphasis added); Alfacell Form 10-Q, filed June 9, 2006, at 19 (same); Alfacell Form 10-Q, filed Mar. 13, 2006, at 19 (same); Alfacell Form 10-Q, filed Dec. 12, 2005, at 17 (same); Alfacell

Form 10-K, filed Oct. 14, 2005, at 26 (same); Alfacell Form 10-Q, filed June 9, 2005, at 16 (same). When Alfacell began offering estimates as to the end-date for the Phase III trial, it tempered its statements with ongoing disclaimers that it was unable to predict the end-date of the trial with certainty. See, e.g., Alfacell Form 10-Q, filed Mar. 12, 2007 ("The primary endpoint of the trial is overall survival. . . . At this time, we cannot predict with certainty the timing of the occurrence of the required number of deaths, but currently estimate that this will occur in the third quarter of 2007.").

Shogen and Kenyon, when meeting with investors on behalf of Alfacell, similarly tempered their statements about the completion of the Phase III trial. As discussed above, Shogen and Kenyon met with investors on June 5, 2007 at a conference in Chicago. While there, they discussed the progress of and potential end-date for the trial. (Am. Compl. at ¶ 49.) Before beginning their discussion, however, Shogen and Kenyon presented a slide that stated:

This presentation includes statements that may constitute "forward-looking" statements, usually containing the words "believe," "estimate," "project," "expect" or similar expressions. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include the risks discussed in the Company's periodic filings with the Securities and Exchange Commission. . . .

Alfacell Form 8-K, EX-99.1, filed on June 5, 2007, at 2.

Alfacell also continued to provide such disclaimers to its investors in its SEC filings. See, e.g., Alfacell Form 10-K, filed June 8, 2007, at 18 ("At this time, we cannot predict with certainty the timing of the occurrence of the required number of deaths, but currently estimate that this will occur in the third quarter of 2007.").

Love alleges that he relied on Alfacell's predictions as to the end-date of the Phase III trial, and that, but for those predictions--and but for the related omission of information pertaining to Alfacell's inability to accurately forecast the end-date of the Phase III trial until sometime in 2008--he would not have exercised his options and purchased 125,000 shares of Alfacell stock on July 17, 2007. He also claims that he did not learn of Defendant's inability to accurately predict the end-date for completion of the Phase III trial until he received and read Kenyon's March 3, 2008 e-mails. Despite Alfacell's repeated warnings that it could not predict the timeline for patient deaths with accuracy, Love contends that he "reasonably relied upon the [alleged] misstatements because Love believed that, with the establishment of [the Committee], providing watchful and responsible care . . . the timeline for completing the confirmatory Phase [III] registration trial . . . was reliable."

(Am. Compl. at ¶ 82.)

Given the total mix of information available to Love, which was publicly available to and accessible by all investors, the Court has determined that Love's reliance upon the aforementioned statements was unreasonable. A reasonable investor, viewing all of the information made available by Alfacell, would not have considered Alfacell's projections as "having significantly altered the 'total mix' of information made available" about Alfacell to the investing public. See TSC Indus., 426 U.S. at 449. A reasonable investor would, instead, have considered such predictions in light of the repeated disclaimers regarding its inability to provide accurate forecasts and, as such, would not have made investment decisions based upon those forecasts.¹³

¹³ Because the Phase III trial was a survival study, the Court notes that Alfacell's inability to accurately forecast an end-date for the trial--that is, Alfacell's inability to determine when patients in the study would die--may have induced reasonable investors to purchase Alfacell stock. A prolonged Phase III trial could be indicative of ONCONASE's efficacy.

The Court further notes that the statements discussed in this subsection likely qualified as "forward-looking statements," protected by Alfacell's repeated warnings and disclaimers and thus shielded by the safe harbor provisions of the PSLRA. The Court will not, however, further explore this theory because the parties have not raised or briefed it.

Finally--although the Court does not rely upon this note in resolving the motion--the Court notes that Love's assertion that he first learned of Alfacell's inability to accurately project an end-date for the Phase III trial, read in light of the entire Amended Complaint and all of the allegations and materials considered, lacks credibility. (See Am. Compl. at ¶ 74.) Love electronically signed several of the SEC filings discussed above, certifying Alfacell's disclosures therein regarding its inability to accurately predict a time line or end-date for the Phase III trial. See, e.g., Alfacell Form 10-Q, filed Dec. 11, 2006.

B. Claims Raised Under Section 20(a)

Love alleges that the Individual Defendants, by nature of their "direct and supervisory involvement in the day-to-day operations of Alfacell," "are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations" alleged in the Amended Complaint. (Id. at ¶ 147.) He alleges, accordingly, that the Individual Defendants are control persons of Alfacell under Section 20(a). (Am. Compl. at ¶¶ 146-48.) Love, however, has not pleaded facts adequate to establish that Alfacell is liable under Section 10(b) or Rule 10b-5 with the particularity required by the PSLRA. Thus, because there can be no liability for the underlying company, there can be no "controlling person" liability under Section 20(a) for any of the Individual Defendants. See In re Suprema Specialties, Inc., 438 F.3d at 287; Chubb Corp., 394 F.3d at 159 n.21.

CONCLUSION

The Court, for the reasons detailed above, will dismiss Plaintiff's claims under Section 10(b), Rule 10b-5, and Section 20(a), with prejudice. Because Love has already amended his Complaint once, and because it appears that he has already included all of the facts available to support his claims, allowing him to take another bite at the apple would be fruitless. See Treppel v. Biovail Corp., No. 03-3002, 2005 WL

2086339, at *12 (S.D.N.Y. Aug. 30, 2005); see also In re Alpharma Inc. Sec. Litig., 372 F.3d 137, 153-54 (3d Cir. 2004) (noting futility of further amended pleadings).

The Court will also dismiss Love's remaining claims--i.e., his claims for securities fraud under Section 49:3-71 of the New Jersey Uniform Securities Law, N.J.S.A. § 49:3-71, fraud, negligent misrepresentation, breach of fiduciary duties, gross negligence, and corporate waste, and his demand for an accounting--as such claims arise under state law, pursuant to 28 U.S.C. § 1367(c)(3). See 28 U.S.C. § 1367(c)(3); Figueroa v. Buccaneer Hotel, 188 F.3d 172, 181 (3d Cir. 1999). The Court will dismiss these claims, however, without prejudice to Love to recommence the action, insofar as it concerns these claims, in state court within thirty days of the entry of the Court's Order and Judgment. 28 U.S.C. § 1367(d). The Court offers no opinion on the merits or the viability of these claims and will not address the part of the motion seeking dismissal of these claims.

The Court will issue an appropriate order and judgment.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: October 17, 2011